

## REMARKS

Claims 78, 98-115 and 119-123 are pending in the present application. Claims 1-77, 79-97 and 116-118, have been previously canceled without prejudice or disclaimer. Claims 124-127 have been newly added.

Applicants, by canceling or amending any claims, make no admission as to the validity of any rejection made by the Examiner against any such claims. Applicants reserve the right to reassert any of the claims canceled and/or the original claim scope of any claim amended, in a continuing application.

New claim 124 is directed to the “method according to claim 78, wherein a maximum dimension in each of two mutually perpendicular cross-sections 2.5 centimeters.” New claim 125 is directed to the “method according to claim 124, wherein the sample further comprises a freezing extender.” New claim 126 is directed to the “method according to claim 125, wherein the freezing extender comprises glycerol.” New claim 127 is directed to the “method according to claim 125, wherein the temperature of the sample is changed in an equiaxial manner.” Support for new claims 124-127 can be found throughout the specification and claims as originally filed.

No new matter has been added

In view of the following, further and favorable consideration is respectfully requested.

***I. At page 2 of the Official Action, claims 78, 98-115 and 119-123 have been rejected under 35 USC § 112, first paragraph as failing to comply with the enablement requirement.***

The Examiner asserts that the specification does not reasonably provide enablement for the freezing of any biological matter, particularly with no cryoprotectant.

In view of the following, this rejection is respectfully traversed.

Applicants respectfully submit that the specification, figures, and examples, provide ample guidance to the skilled artisan in view of the state of the art at the time the application was filed, to make and use the claimed subject matter without undue experimentation.

Additionally, Applicants note that the court in *In re Wright* held that nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples.

Applicants submit that reading the present claims in view of the specification a skilled artisan would be able to make and use a method of freezing a biological material selected from the group consisting of semen, blood, blood cells, blood constituents and umbilical cord blood, with or without a cryoprotectant, as claimed, without undue experimentation.

In support of this position, Applicants once again politely refer the Examiner to the text of the present specification and Attachment A, which was submitted with Applicants' November 6, 2008 Amendment and Response. In this regard, Applicants note that present specification describes the possibility of freezing without a cryoprotectant. Further, Attachment A provides evidence that the present method of freezing is enabling for the full

scope of the Markush group of biological agents and by specific example of showing freezing of red blood cells, umbilical cord blood cells and bone marrow cells. Applicants respectfully submit that taken together, a skilled artisan would be able to practice the claimed subject matter without undue experimentation. Rather than repeating the remarks submitted in the previous response, Applicants hereby incorporate the remarks herein by reference. For a complete discussion regarding the enablement of the present claims, please see Applicants November 6, 2008 Amendment and Response.

In view of the foregoing, Applicant submits that the specification enables the skilled artisan to make and use the full scope of claims 78, 98-115 and 119-123, within the meaning of 35 USC § 112, first paragraph. Thus, the Examiner is respectfully requested to withdraw this rejection.

***II. At page 7 of the Official Action, claims 78, 98-100, 102, 106, 144 and 123 have been rejected under 35 USC § 102(a) as being anticipated by Arav et al. (reference U, of record referred to hereinafter as "the Arav publication") in view of the Baxter Catalog (reference V, of record).***

The Examiner asserts that Arav publication anticipates the subject matter of claims 78, 98-100, 102, 106, 114 and 123.

Applicants respectfully submit that this rejection is moot since the Arav et al. publication is not proper prior art against the present claims within the meaning of 35 USC § 102(a). Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

**III. At page 5-7 of the Official Action, claims 78, and 98-110, 114, 115 and 119-123 have been rejected under 35 USC § 103 (a) as being unpatentable over US Patent No. 5,873,254 (the '254 patent), both alone and in combination with US Patent No. 4,131,200 (the '200 patent) in view of Dayian et al. (reference V2 of record).**

The Examiner asserts that although the '254 patent does not describe the size of the sample as presently claimed, the generic description in the Summary of the '254 patent is not limited with regard to the size of the sample. With regard to combination of the '254 patent with the '200 patent and Dayian et al., the Examiner asserts that the substitution of the controlled freezing method described in the '254 patent for the uncontrolled platelet freezing method described in the '200 patent would have been obvious to a person of ordinary skill in the art.

In view of the following, this rejection is respectfully traversed.

To establish a *prima facie* case of obviousness, the PTO must satisfy three requirements. First, as the U.S. Supreme Court held in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of

necessity will be combinations of what, in some sense, is already known.” (KSR, 550 U.S. 398 at 417.) Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

Applicants can rebut a *prima facie* case of obviousness based on overlapping ranges by showing the criticality of the claimed range. "The law is replete with cases in which the difference between the claimed invention and the prior art is some range or other variable within the claims. . . . In such a situation, the applicant must show that the particular range is critical, generally by showing that the claimed range achieves unexpected results relative to the prior art range." *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). See MPEP § 2114.05(III).

It is submitted that a proper case of *prima facie* obviousness has not been established because all the elements of the presently claimed subject matter are neither taught nor suggested by the '254 patent, '200 patent or Dayian et al., whether taken alone or in combination. In addition, Applicants submit that even if a case of *prima facie* obviousness were established, a *prima facie* of obviousness would be rebutted because the presently claimed subject matter exhibits unexpectedly superior results in as much as the presently claimed subject matter provides for freezing of large samples, where the sample size is critical.

From the outset, Applicants respectfully submit that the presently claimed subject matter is directed to methods of freezing large samples of biological matter selected from the group consisting of semen, blood, blood cells, blood constituents and umbilical cord blood, which is in the form of a sample having a minimal dimension in each of two mutually perpendicular cross-sections exceeds 0.5 centimeters. In contrast, none of the '254 patent, the '200 patent or Dayian et al. teach or suggest the presently claimed methods, namely the changing the temperature presently claimed sample size as recited in the present claims.

However, assuming *arguendo* that the '254 patent, the '200 patent or Dayian et al. did teach or suggest every element of the presently claimed subject matter, Applicants respectfully submit that the presently claimed subject matter results in the unexpectedly superior results of making it possible to freeze and thaw viable biological matter in the presently claimed sample size.

In view of the remarks set forth herein, it is submitted that, whether taken alone or in combination none of the cited references render the presently claimed subject matter obvious within the meaning of 35 USC § 103 (a). Accordingly, the Examiner is respectfully requested to withdraw this rejection.

**IV. At page 9 of the Official Action, claims 78, and 98-110, 114, 115 and 119-123 have been rejected under 35 USC § 103 (a) as being unpatentable over the Arav publication in combination with the '254 patent in light of Swanson et al. (reference W of record) and the Baxter catalog.**

The Examiner asserts that the cited references render the claimed subject matter obvious for the reasons set forth in the Official Action

In view of the following, this rejection is respectfully traversed.

Applicants respectfully submit that this rejection is moot because the Arav publication is not prior art against the presently claimed subject matter. Since the remaining references do not teach or suggest every element of the claimed subject matter. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

**V. New Claims 124-127**

New claim 124 is directed to the “method according to claim 78, wherein a maximum dimension in each of two mutually perpendicular cross-sections 2.5 centimeters.” New claim 125 is directed to the “method according to claim 124, wherein the sample further comprises a freezing extender.” New claim 126 is directed to the “method according to claim 125, wherein the freezing extender comprises glycerol.” New claim 127 is directed to the “method according to claim 125, wherein the temperature of the sample is changed in an equiaxial manner.”

Applicants respectfully submit that new claims 124-127 are novel and non-obvious. Accordingly, Applicants respectfully request an indication that all of the pending claims are now allowable.

**CONCLUSION**

In view of the foregoing, Applicant submits that the application is in condition for immediate allowance. Early notice to that effect is earnestly solicited. The Examiner is invited to contact the undersigned attorney if it is believed that such contact will expedite the prosecution of the application.

In the event this paper is not timely filed, Applicants petition for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

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Date: June 16, 2010  
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